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METHOD AND INSTRUMENTS FOR REPAIRING ENDOCHONDRAL AND OSTEOCHONDRAL DEFECTS

[Verfahren und Instrumente für die Reparatur von endochondralen und osteochondralen Defekten]

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Endochondral or osteochondral defects, especially joint cartilage defects are repaired by making cylindrical holes (21) in the area of the defect and implanting columns of tissue (2) with a vital cartilage layer (2') on one front surface, said columns of tissue (2) being taken for example from a less strained joint site. The chances of success of this type of reparation are improved by increased precision. To this end, a guiding instrument for precisely guiding cutting or boring instruments is used for making the holes (21). Said guiding instrument can be positioned and fixed in the area of the defect. Consequently it is possible to achieve a high degree of precision in terms of the parallelism and the position of the holes (21). It is also possible to reconstruct an original cartilage surface very accurately by determining an original cartilage surface and then matching the axial length and the angle between the cartilage surface and the column axis of the column of tissue (2) to be implanted to this original surface. Gaps between the implanted tissue columns (2) and on the edges of the defect in the reconstructed cartilage surface are also filled using another implant from a layer of cartilage (50) grown in vitro.

This invention is in the field of medical technology and /1
relates to a method and instruments in accordance with the precharacterizing parts of the respective Claims. The methods and instruments serve to repair endochondral and osteochondral defects, in particular defects that affect the joint cartilage or joint cartilage and bone tissue beneath it.

Defects in joint cartilage or defects that affect joint cartilage and the bone tissue beneath it are repaired in accordance with the prior art by filling them with material containing artificial, optionally vital, cells, in that cartilage tissue grown in vitro is implanted or in that cartilage tissue is removed from intact, preferably unstrained sites, and implanted as an autotransplant at the defective site. The autotransplants, in particular, are mostly columns having an outer cartilage face side and an inner bone face side. For larger defects, a plurality of such columns are usually implanted side by side in the manner of a mosaic.

For implanting tissue columns, cylindrical holes are produced /2
in the region of the defect that are defined as precisely as possible, whereby a tissue cylinder is punched or drilled out and then separated by rotating it on its base or by using a chip-removing drill. Tissue

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* Numbers in the margin indicate pagination in the foreign text.

columns are then removed from a less strained joint site (e.g. the condyle region of the femur), the columns having a diameter slightly greater than the inner diameter of the hole seated in the region of the defect. The tissue columns that are to be removed are drilled out with a drill and then removed by twisting at the base. The tissue columns that are removed are then inserted into the defect holes and, thanks to the difference in diameter, a so-called "press fit" is produced, by means of which the columns are held in the holes. The holes caused by removing the columns are normally filled with material that is removed from the defect, if this material is in a good state of health, or they are closed off by inserting artificial materials or material cultivated in vitro.

For dislodging and removing the tissue columns that are to be implanted and optionally for stamping out or removing the tissue from the hole in the defect region, tubular instruments are typically used that have on one face side a ring-shaped cutting edge and equipment for holding and guiding on the other end. For checking the length and quality of the tissue column that has been stamped out, such an instrument advantageously has a corresponding window. The material that has been stamped out is pushed out of the tubular instrument with the help of a plug matching the inner diameter of the instrument. Such instrument sets are commercially available, manufactured, for example, by Smith & Nephew. Inc., USA, or by Arthrex Inc., USA. A flat drill can be used to drill the holes in the defect region.

It has been found that the success of the methods described /3
above for repairing joint cartilage defects by implanting vital tissue is greatly dependent on the precision with which the repair tissue is inserted and by the treatment to which the tissue was subjected while being removed and implanted.

Thus, the object of this invention is to improve known methods and instrument sets for repairing cartilage defects or defects that involve cartilage and the bone tissue beneath it, in particular joint cartilage defects, by implantation or transplantation of vital tissues in column form, in order to increase the chances of success. The methods and instruments of this invention should make it possible to increase the precision of the repair, while at the same time treating the manipulated tissue with great care. The instruments of this invention should, nevertheless, be simple to manufacture and particularly easy to handle. The methods and devices of this invention should be particularly well suited to repairing larger defects using a mosaic method, but of course they should also be applicable, at least in part, to small defects that can be repaired with just one implant.

This object is achieved by the methods and instruments defined in the independent claims. The dependent claims define additional embodiments.

It was found that solving the above-mentioned general task requires efforts toward improvement in four partial aspects, whereby, depending on the application, one of the improvements has the greatest effect and the other aspects have a minor effect or no perceptible effect and, consequently, can be omitted. The four main aspects for improvement are the following: /4

- When implanting a plurality of tissue columns, the precision of the positioning and parallelism of the cylindrical holes produced in the region of the defect must be increased. This is achieved in that the holes are produced using the proper gauge. This measure generally prevents tissue columns implanted in the holes from pressing against one another, causing them to be subjected to additional loads, and it assures that, at least in the region in which it is anchored in healthy tissue, each implanted column will be surrounded as much as possibly by native tissue, which promotes healing of the wound.

- With the cartilage surface of the repaired defect, the topography of the original, i.e., the healthy or defect-free cartilage surface is recreated with improved precision. In order to achieve this object, the axial length of the tissue columns that are to be implanted and, to the extent possible, the alignment of the cartilage surface relative to the column axis are oriented toward the cartilage surface that is to be recreated. This measure is particularly important in the case of relatively large defects, which must be repaired with a plurality of implant columns. The better the original cartilage surface recreated, the more uniformly the surfaces of the individual implants will be strained when the repaired joint is used and the more uniform the overall load on the individual implants will be distributed. In this way, undesired deformations and injuries of the implant and of the native cartilage around the repaired defect, as aftereffects of the repair, can be prevented.

- The cartilage surface of the repaired defect is made with fewer gaps and aligned with fewer gaps with the native cartilage. The gap-free nature of the cartilage surface is produced with a combination of transplanted or implanted tissue columns and in vitro cultivated cartilage tissue, with the gaps between the implanted tissue columns and optionally gaps between the tissue columns and the native cartilage filled in. A gap-free cartilage surface promotes fusion of the implant and the native cartilage and prevents secondary damage that can arise if synovial fluid passes through gaps in the /5

cartilage layer to the to the bone tissue beneath it. This measure is also important for larger defects that must be repaired with a plurality of transplant columns, while the above-mentioned "press fit" is sufficient for smaller defects.

- During both harvesting and implanting, the material that is to be implanted is handled with care and, in particular, with as little pressure as possible, so that uncontrolled deformation of the transplanted tissue column and, optionally, of the implant portion cultivate in vitro can be prevented and, thus, the precision of the repair can be improved.

In any case, the implanted tissue columns are advantageously autotransplants removed from a less strained site, but may also be of bone-replacement material, on which in vitro cartilage tissue has previously been cultivated. Such columns to be implanted are also advantageously produced during the repair operation from correspondingly prepared pieces by stamping or drilling (drill).

The processes and instruments of this invention are suitable for both repair operations that are carried out as open surgery and for arthroscopy. /6

Exemplary embodiments of the improved method and the improved instrument sets for repairing endochondral or osteochondral defects, in particular in joints, will now be described in greater detail in conjunction with the following figures.

The figures show:

Figure 1: a schematic representation of a cartilage defect repaired in accordance with the known mosaic method, top view and cross section, for explaining the aspects of improving the precision of positioning and parallelism of the holes produced in the region of defect,

Figure 2: an exemplary embodiment of a gauge for producing holes in the region of a defect to be repaired, as in Fig. 1,

Figure 3: a schematic representation of a cartilage defect for explaining the aspects of improving the reconstruction of the original cartilage surface by the proper axial length of tissue columns that are to be implanted and an exemplary gauge for reconstructing the original cartilage surface,

Figure 4: an exemplary embodiment of an instrument for determining the distance between the original cartilage surface and the base

surface of a hole produced in the region of a defect that is to be repaired in accordance with Fig. 3,

Figure 5 and figure 6: /7
schematic representation of a cartilage defect (Fig. 5) and a removal site (Fig. 6) for explaining improvements in the reconstruction of the original cartilage surface by the corresponding adaptation of the angle between the cartilage surface and the axis of a tissue column that is to be implanted,

Figure 7: an exemplary embodiment of an instrument for removing and implanting tissue columns with a predetermined angle α between cartilage surface and column axis,

Figure 8: a gauge in accordance with Fig. 2, equipped for the implantation of tissue columns in a predetermined rotational position,

Figure 9 and figure 10:
schematic representations of a repaired cartilage defect in the form of a top view (Fig. 9) and cross section (Fig. 10), for explaining improvements in the gap-free nature of the repaired cartilage surface,

Figure 11: an exemplary embodiment of a punching tool for producing an implant from cartilage tissue cultivated in vitro for a repair in accordance with Figs. 9 and 10,

Figure 12: an exemplary embodiment of an instrument for determining /8
the layer thickness of cartilage cultivated in vitro,

Figures 13 through 16:
an exemplary embodiment of cooperating instruments (Figs. 13 through 15 in cross section parallel to axis) for careful removal and implantation of tissue columns,

Figure 17: the instruments in accordance with Figs. 13, 15, 16 in three-dimensional representation,

Figure 18: an embodiment of an implant guide with recesses in the face surface for accommodating a stop pin provided on the extractor, and

Figure 19: an embodiment of a plunger for ejecting a tissue column from the extractor.

Figure 1 shows a top view (left) and a cross section (right) of a cartilage defect repaired using the known mosaic method. In the top view, the surface of native cartilage layer **1** may be seen, along with the round surfaces of cartilage layers **2'** of the implanted tissue columns **2** used for the repair. The cross section also shows native bone tissue **3** under native cartilage layer **1**, as well as implanted tissue columns **2** in correspondingly cylindrical holes, the columns having an inner bone part **2"** under cartilage layer **2'** which, in the case of transplanted columns consist of bone tissue and in the /9
case of columns cultivated in vitro consist of a bone-replacement material.

In order to produce a repaired cartilage surface with gaps as small as possible or with regions of defective cartilage material that are as small as possible, as close an arrangement of the columns is usually sought. For this reason, it is important that the holes for columns **2** to be implanted be as precisely parallel as possible. With highly precise parallelism, it can be assured that the holes can be placed very close to one another, but without intersecting, which would make the implantation more difficult and place the implanted columns under additional loads. If, as will be described below in conjunction with Figs. 9 and 10, the spaces between columns **2** is to be filled with an additional implant, then a high degree of precision is needed not only with respect to the parallelism between holes, but also with respect to the positioning of the holes.

Figure 2 shows an exemplary embodiment of a guide instrument that can be used to produce a plurality of cylindrical holes in the region of a cartilage defect with much greater precision than by the visual estimate of the surgeon, as has been done in the past. The exemplary embodiment of the guide instrument shown is suitable for making a repair as shown in Fig. 1. It consists essentially of a hollow cylindrical circular guide **10** and at least two tubular stamping or drilling guides **11** and **12**, all of which are shown in top view (like the top view of the repaired defect at the left in Fig. 1).

Circular guide **10** is positioned around the defect and fastened, using Kirschner's wire for example through holes **13**, which are designed for this purpose, or by some other suitable fastening means. /10
Thus, from a set of circular guides, those are selected whose inner surface is of such a shape and size that it corresponds as precisely as possible to the defect that is to be repaired. Stamping or drilling guides **11** and **12** have an inner diameter that is adapted to the stamping or drilling instrument that is to be used and, for exact positioning in circular guide **10**, they have on the outside, for example, at least one axially extending neck **14**, which fit in axially extending grooves **15** on the inner surface of circular guide **10**,

whereby the radial height of the neck(s) **14** is adapted to the distance between the inner surface of circular guide **10** and a hole that is to be produced. In Fig. 2, stamping or drilling guide **10** is intended for producing the central hole of the repair shown in Fig. 1 and stamping or drilling guide **12** for producing the peripheral holes.

Both guides **11** and **12** have two necks **14**, which may be positioned in opposite grooves **15** of circular guide 10. With the proper design of grooves and necks, it is also possible to provide only one neck for each stamping or drilling guide.

The guide instrument shown in Fig. 2 is provided for an approximately circular defect. Similarly, guide instruments can be provided for defects of other shapes.

Circular guide **10** of the guide instrument in accordance with Fig. 2 is fastened in position around the defect that is to be repaired using Kirschner's wire, for example. In order to prevent additional strain on the defect region when attaching circular guide **10**, circular guide **10** can also be attached, for example, by means of three-point fixation at a point on the same bone on which the defect is to be repaired, at a point remote from the defect site. Such /11
attachments are known from joint prosthetic surgery. They may be used for both open surgery and for arthroscopy.

In order to restrict the view of the surgeon as little as possible while he is making the holes, at least circular guide **10** advantageously consists of a clear material or has a corresponding window.

The guide instrument shown in Fig. 2 is an exemplary embodiment of such an instrument. In general, such a guide instrument has means with which it can be positioned in the region of a defect that is to be repaired and it has means for guiding stamping or drilling instruments to a plurality of positions.

In addition to the stamping or drilling instruments for producing the holes for implantation of the tissue columns, an instrument set in accordance with this invention for repairing cartilage defects also has a set of various guide instruments, optionally designed specifically for the joint that is to be treated and for the defect that is expected. The surgeon who is making the repair selects from the set of guide instruments the appropriate one, positions circular guide **10** on the defect, and secures it. He then inserts a stamping or drilling guide **11** or **12** into circular guide **10** and uses it to guide the stamping or drilling instrument being used to produce the

corresponding hole. For making additional holes, the stamping or drilling guide is replaced or its position is changed.

Figure 3 shows a cross section of a cartilage defect **20** at a highly arched joint site. Defects of such dimensions are not uncommon in knee and hip joints. Defect **20** and three holes **21** produced in the region of the defect are shown, for example, with the guide instrument in accordance with Fig. 2. The original cartilage /12
surface **22**, which is to be restored as precisely as possible with the repair, is indicated by the dot-dashed line. Figure 3 clearly shows that a measurement of the depth of the holes in the defective region for determining the axial length of the tissue columns needed for the repair presents a poor approximation.

To improve the approximation, it is proposed that original cartilage surface **22** be approximated with the help of a profile gauge **23**. In the process, before the hole is made the gauge **23** that best fits the defective cartilage region is selected by applying various such gauges **23** from a corresponding gauge set.

Gauges **23** of the gauge set can be, for example, simple one-dimensional radius gauges, by means of which the original cartilage surface **22** is approximated as a spherical surface. However, one- or two-dimensional gauges **23** are also conceivable that are adapted to common sizes and shapes of certain joint regions.

Figure 4 shows an exemplary embodiment of an instrument for determining the axial length of tissue columns for implantation in holes **21**, which have been made in defect **20** as seen in Fig. 3. The manner of representation is the same as in Fig. 3 and the instrument for determining the column lengths is shown in axial section. The instrument essentially comprises a circular guide **10**, a surface template **24**, and a measuring rod **25**.

Once the holes have been prepared with the help of the guide instrument as in Fig. 2, circular guide **10** of this instrument advantageously serves as a circular guide for the length /13
determination. A surface template **24** is positioned on top. This surface template **24** is the template from a set of variously shaped templates **24** that corresponds in shape (curvature) to the gauge **23** that was selected before the holes were made for reconstructing original cartilage surface **22** it has a pattern of measurement holes **26**, which correspond to the pattern of holes **21** that are made. For example, with positioning cams **27**, which fit into grooves **14** of circular guide **10**, measurement holes **26** of surface template **24** are aligned on the pattern of holes **21**.

It is also possible to use measuring template **24** directly as profile gauge **23**. In this case, it is advantageous if it consists of a transparent material.

Measuring rod **25** has a diameter that is adapted to measurement holes **26** and has a measurement scale **28** that takes into account the distance between original cartilage surface **22** and measuring template **24**. The length of the tissue columns needed for making the repair can be read directly on measurement scale **28**, for example, to within a half-millimeter.

For simple assignment of each profile gauge **23** of a gauge set to a certain measuring template **24** of a template set, they are marked accordingly, for example with a color code. Since measuring templates **24** run parallel to an original cartilage surface **22** and the distance between this surface and the measuring template essentially corresponds to the axial height of circular guide **10**, one measuring rod **25** is sufficient for all measurements. So as to assure that the same hole depth can always be measured for holes at an oblique angle between the axis of the hole and original cartilage surface **22** /14
(peripheral hole of the defect, as in Fig. 3), measuring rod **25** and measurement holes **26** can be provided with axially extending grooves and necks (not shown in Fig. 4), by means of which measuring rod **25** can be inserted in a measuring hole **26** only in a certain rotational position.

The instruments shown in Figs. 3 and 4 for determining the original topography of a defect region and for determining the length of tissue columns for repairing the defect are exemplary embodiments. In general, such instruments have profile gauges for determining the topography and means adapted to the profile gauges for determining the column lengths, whereby the profile gauges themselves may be part of the means for determining the column lengths.

A surgeon who is to repair the defect shown in Fig. 3 proceeds in accordance with the following steps:

- Determination of the surface template **24** that corresponds to the defect, optionally using a gauge **23**;

- Positioning and assembly of circular guide **10**;

- Making holes **21**, optionally with the help of guides **11** and **12**;
- Positioning of surface template **24** and determination of the lengths of the tissue columns that are to be implanted;

- Adjustment of stamping and drilling instruments to the predetermined axial length for removing tissue columns;

- Removal of the columns at a removal site and implantation in the holes.

Figure 5 shows the same defect as Fig. 3 at a highly arched joint site. It may be seen in Fig. 5 that original cartilage surface **22** can be reconstructed with a high degree of precision, if angles $\alpha.1$, $\alpha.2$, and $\alpha.3$ between the original cartilage surface and the axis of holes 21.1, 21.2, and 21.3 are not left to chance, but are reconstructed /15 deliberately. Thus, for a greater chance of a successful repair, it is advantageous to determine the angles α for the various tissue columns that are to be implanted and to selectively take corresponding tissue columns from another site or to stamp them out of cartilage cultivated in vitro.

For removing tissue columns to be transplanted, it would be simplest to seek a removal site that corresponds in shape to the defective region and to remove the tissue columns in a device that is identical to the device used for the holes in the defective region.

However, this is not only not advantageous, but actually impossible. In particular, the low-stress condyle region of the femur, which has its own shape, is available for removal and it is advantageous to make the removals in a row and keep the distances between removal sites as large as possible.

For this reason, for a precise reconstruction of original cartilage surface **22**, the angles α should be determined and the columns should be removed at a corresponding angle at the removal site.

Figure 6 shows such a removal site and tissue columns 2.1, 2.2 and 2.3 to be removed, corresponding to holes 21.1, 21.2, and 21.3, whereby the angles α between the cartilage surface and the column axis correspond to the angles $\alpha.1$, $\alpha.2$, and $\alpha.3$.

For removing tissue columns 2.1, 2.2, and 2.3 in accordance with Fig. 6 and for implanting them in holes 21.1, 21.2, and 21. as in Fig. 5, an instrument is provided, with which a column having a /16 predetermined angle between the column axis and the cartilage surface and a defined rotational position can be removed and implanted in a similarly defined rotational position.

Figure 7 shows an exemplary embodiment of such a removal instrument, which essentially comprises an extractor guide **30** and an extractor **31**.

Extractor guide **30** is essentially tubular and has at one end a application flange **32**, which is aligned at an angle α to the tube axis. Although Fig. 7 shows one exemplary embodiment, in which the angle α to the tube axis is fixed, it is obvious that the instrument can also be made in such a way that this angle α is adjustable. Application flange **32** can have boreholes (not shown) for attachment, attached to the tissue with Kirschner's wire through the boreholes. The extractor guide can also be attached by external three-point fixation, as previously mentioned in conjunction with Fig. 2.

Extractor guide **30** has an inner diameter to match extractor **31** and a guide groove **33** extending axially on the inner surface, running, for example, at the site of the inner circumference corresponding to the highest or lowest point of application flange **32**. In an extended end region **34** of extractor guide **30**, which opens into application flange **32**, the inner diameter is expanded to the radial extension of guide groove **33**.

Extractor **31** is also tubular and has an inner diameter corresponding to the diameter of the column that is to be removed. /17
One face side is pointed in the manner of a blade. On its outer surface extractor **31** has a guide cam **35**, which when extractor **31** is inserted into extractor guide **30** runs in guide groove **33** of extractor guide **30**. This guide cam **35** is arranged axially in such a way that it is positioned in the expanded end region **34** of extractor guide **30** when the pointed face side of extractor **31** has reached the depth in the tissue that corresponds to the length of the column that is to be extracted. Due to the guide cam, extractor **31** can be inserted into extractor guide **30** only in a defined rotational position, but it can be rotated for releasing the column at its base in the extractor guide.

So that, when being dislodged, the column that is to be released does not turn in extractor **31**, the latter has on its inner surface, as close as possible to the pointed face side, at least one twist lock **36** extending radially into the inner space, extending axially and advantageously blade-like. It has been found that the radial extension of such a twist lock need not be greater than a millimeter.

Extractor **31**, which is guided through extractor guide **30**, can be used, as indicated by line S, to punch out a tissue column and to release it at its base by turning. Before extraction, however, it is advantageous to predrill the column with a drill (not shown) along

line S. Such a drill corresponds in shape to extractor **31**, but without guide cam **35** and twist lock **36**. The pointed edge is advantageously made of a diamond-containing material or coated with such a material. The drill also has suitable means for determining the depth of the borehole.

Figure 7 also shows a plunger **37** for ejecting an extracted tissue column from extractor **31**. The plunger advantageously has a distal face surface that, like application flange **32**, forms an angle α to the plunger axis. So that plunger **37** can be inserted into the /18
extractor only in the rotational position corresponding to the flange position, it has an axially extending guide groove **38** and extractor **31** has a corresponding guide ridge **39**, which however does not reach into the region of a tissue column positioned in the extractor. The distal end of plunger **37** has a reduced diameter, so that it can be pushed past twist lock **36** to the end of extractor **31**.

Figure 8 shows an implantation instrument for implanting the tissue column that has been removed with the removal instrument in accordance with Fig. 7. A top view of the instrument is shown. There is an implant guide **40**, which is made the same as stamping or drilling guides **11** and **12** in Fig. 2, and it is positioned in the same circular guide **10** (indicated by the dot-dashed circle). The inner diameter of implant guide **40** matches the outer diameter of extractor **31**. So that extractor **31** can be inserted in implant guide **40** only in the predetermined rotational position, the latter has on its inner surface an axially extending guide groove **41**, in which guide cam **35** of extractors **31** can be positioned.

Angles α of the tissue columns that are to be implanted are unambiguously determined by the shape of the previously selected surface template **24** (Fig. 4) for each column. Thus, the surgeon needs only one removal instrument with a set of various extractor guides **30**, which can be correlated with the corresponding measurement hole of the surface template or with the corresponding hole in the defect region, for example by means of a code. Various numbers of marks for various pairs of measurement holes and extractor guides to be correlated are possible as a code for a surface template, whereby the
marks are of different colors for different surface templates. /19
Extractor guides **30** can also be marked with the size of angle α and the same sizes can be marked beside the measurement holes on the surface templates.

The instruments in Figs. 7 and 8 are exemplary embodiments. In general, a removal instrument for column removal with a predetermined angle between the cartilage surface and the column axis has means that can be fixed at a removal site for guiding an extractor and,

optionally, a drill at the predetermined angle and an implanting instrument, whereby the removal instrument and the implanting instrument have correlating means for removal and implantation in a correlated rotational position.

Thus, for reconstructing the angle between the column axes and the original cartilage surface, a surgeon will read on surface template **24** which extractor guide **30** he should use for the removal of each tissue column. He mounts extractor guide **30** on a suitable removal site, predrills the tissue column through extractor guide **30** with internal and external cooling, drives an extractor **31** into the predrill, loosens the tissue column by turning the extractor from its base, rotates extractor **31** back into its original rotational position, and removes extractor **31** with the tissue column from extractor guide **30**. He then inserts implant guide **40** into circular guide **10**, which is still mounted on the defect region, pushes the extractor with the tissue column into implant guide **40**, and pushes the tissue column with the help of plunger **37** into the hole positioned under the implant guide, which he has previously made, as described for example in connection with Figs. 1 and 2.

The axial length of the removed tissue column is determined /20
separately, if means are provided for adjusting the drilling depth and the insertion depth of the extractors into the tissue. Nevertheless, it may be advantageous to check and optionally correct this length before implantation. For this purpose, windows are provided in extractor **31** (see also Figs. 13 and 17), which are arranged in such a way that the cartilage surface of the removed column comes to lie in the region of the windows, and length scales are placed in the region of the windows for determining the distance between the pointed edge of the extractors and the cartilage surface of the tissue column. If the removed tissue column is too long, it is pushed forward slightly with the help of plunger **37** and the part protruding out of the extractor is cut off.

Figures 9 and 10 show a top view and a cross section of a repaired cartilage defect which, in addition to implanted tissue columns **2**, also contains an implanted, in vitro cultivated cartilage layer **50**. Cartilage layer **50** fills the gaps between tissue columns **2** and those between tissue columns **2** and native cartilage layer **1**. Where the defect is deeper than the thickness of cartilage layer **50**, implanted cartilage layer **50** is backfilled with a suitable filler material **51**.

The main advantage of the repair in accordance with Figs. 9 and 10 with implanted cartilage layer **50**, compared to the repair in accordance with figure 1 without such a cartilage layer is that with

cartilage layer **50** the gaps between implanted tissue columns **2** are completely closed, so that the penetration of synovial fluid onto the bone tissue can be prevented. In this way, the columns can also be implanted somewhat farther away from one another with no disadvantage, so that they are surrounded by native bone tissue, which significantly accelerates the complete fusion of native and implanted tissue.

The advantage of the repair in accordance with Figs. 9 and 10 /21
with implanted cartilage layer **50** and transplanted tissue columns, compared to a repair using only a cartilage layer cultivated in vitro (optionally backfilled with a suitable material), is that with the transplanted cartilage, which also has sufficient mechanical strength, it absorbs a large part of the load, so that immediately following the repair operation the in vitro cultivated cartilage can mature under mild conditions (little stress) and thus can achieve its final mechanical strength, equal to that of the native cartilage.

Cartilage layer **50** is cultivated in advance from autologous cells, either on a substrate of bone-replacement material or without such a substrate. In this way, the shape of the resulting cartilage is determined by the space made available to the cells during cultivation.

For implantation, in vitro cultivated cartilage layer **50** must be stamped or cut as precisely as possible in the shape corresponding to a hole produced in the region of the defect that is to be repaired and holes must be made there for the tissue columns, while the holes must have a slightly smaller diameter than the tissue columns for a "press fit." Moreover, for precise backfilling of the cartilage layer or for a corresponding cut in the defect, the thickness of the cultivated cartilage layer must be determined.

For producing the hole for the cartilage layer **50** being implanted, a circular guide **10** (Fig. 2), for example, is mounted in the defect region and the native cartilage tissue along it is cut perpendicularly with a corresponding circular punching instrument or with a scalpel and then removed in such a way that everywhere within the circular guide the cartilage or bone surface lies deeper than /22
the original cartilage surface by at least the thickness of the cartilage layer that is to be implanted.

Figures 9 and 10 show a repair with six rotationally symmetrical tissue columns **2**. Obviously, other column arrangements with different numbers of tissue columns are likewise possible, in particular using just one tissue column.

Figure 11 shows an exemplary embodiment of a stamping instrument for producing a desired implant from cartilage layer **50** for a repair as shown in Figs. 9 and 10. The stamping instrument consists essentially of an application surface **60** and a stamping form **61**. The shape (arch) of application surface **60** corresponds advantageously to the shape of cartilage surface **22** that is to be reconstructed (Figs. 3 and 4) or to surface template **24** (Fig. 4), in accordance with which the cartilage surface is reconstructed. Stamping form **61** has a shape corresponding to that of application surface **60** and has punch blades **62** corresponding to the outline of the implant that is to be made and the holes that are to be made for the tissue columns, whereby the punch blades have a width that is greater than the thickness of the cartilage layer that is to be punched.

To achieve an even more precise punch, it is advantageous to place counter blades (not shown) of very small width on application surface **60** corresponding to punch blades **62** of stamping form **61**.

Cultivated cartilage layer **50** is positioned on application surface **60** and stamping form **61** is moved by suitable driving means parallel against application surface **60**, until punch blades **62** lie upon application surface **60** or on the counter blades and cartilage layer **50** is completely severed at the designated site. /23

Figure 12 shows an exemplary embodiment of an instrument for determining the thickness of an in vitro cultivated cartilage layer **50** (with or without substrate of bone-replacement material). The instrument essentially comprises a measuring unit **70** with molds **71** of various depths and a weighting unit **72**, which is advantageously made of a transparent material and whose weight on the application surface essentially corresponds to the pressure force used in the implantation. recesses **71** advantageously have the shape of a defect that is to be repaired or the shape of a hole that has been made in the region of such a defect for the implantation of cartilage layer **50**.

For a thickness determination, die stamped-out cartilage layer **50** is placed in one of the recesses **71** and weighted down with weighting unit **72**. The thickness of cartilage layer **50** relevant to the implantation corresponds to the depth of the recess **71** on which weighting unit **72** no longer lies when cartilage layer **50** is positioned therein.

Thus, an instrument set of this invention for repairing a defect in accordance with Figs. 9 and 10 has, in addition to at least one part of the instrument described above, an instrument for punching or cutting an in vitro cultivated cartilage layer **50**, with a set of

various pairs of application surfaces **60** and stamping forms **61**. Moreover, the instrument set advantageously has an instrument for measuring the thickness of such a cartilage layer required for the implantation or a set of such instruments for various defect shapes.

For making a repair as illustrated in Figs. 9 and 10, for example, a surgeon performs the following steps in the indicated order: /24

- Determining the shape of the cartilage surface 22 that is to be reconstructed;

- Determining the hole for the cartilage layer **50** that is to be implanted and the pattern of the tissue columns **2** that are to be implanted;

- Production of the implant from an in vitro cultivated cartilage layer **50** and determining the thickness of cartilage layer **50**;

- Assembling a circular guide **10**;

- Making the hole for the cartilage layer **50** that is to be implanted;

- For each tissue column **2**: making a hole **21**, removing a tissue column **2**, implanting tissue column **2** in hole **21**;

- Removing circular guide **10**;

- If necessary, inserting filler materials **51**;

- Implanting cartilage layer **50**.

Figures 13 through 16 represent (Figs. 13 through 15 cross section parallel to the axis) parts of an additional exemplary embodiment of an instruments for removing and implanting tissue columns, namely: Fig. 13 shows an extractor 31.1, Fig. 14 an extractor guide 30.1 for guiding extractor 31.1 when removing the tissue column, Fig. 15 an implant guide 40.1 for guiding extractors 31.1 during implantation of the tissue column, and Fig. 15 a plunger 37.1 for ejecting a tissue column from extractor 31.1.

In many of their characteristics, instrument parts 31.1, 30.1, 40.1, and 37.1 correspond to instrument parts 31, 30, 40, 37 of the same functions as previously described in Figs. 7 and 8. Consequently, only the characteristics by which they differ from the latter will be described here. Additional characteristics are identified with the reference numbers in Figs. 7 and 8.

/25

In the region facing the pointed end, extractor 31.1 has two opposing windows **80** and a length scale **81** for inspection and length measurement of a tissue column that has been extracted. Moreover, on the side of window **80** opposite the pointed end, the extractor is divided into two extractor parts up to its opposite end by two opposingly arranged, axially extending slits **82**. For convenient handling, the end of the extractor opposite the pointed end is equipped with a handle **83**, also divided into two parts, which also limits the insertion depth of extractor 31.1 into a corresponding guide 30.1, 40.1. /25

At this point, it should be pointed out that the twist lock **36** shown in Fig. 7 or the two twist locks in Fig. 13, which prevent the extractor from turning relative to the tissue column when twisting off a tissue column (the tissue column must still be twisted off the bottom, on which is it still "anchored"), can be pulled out much farther than indicated in Fig. 13 or in Fig. 7. In particular, such a twist lock **36** can extend over the maximum length that a tissue column to be removed with the corresponding extractor can have or even over the entire length of the extractor. Extractors with longer twist locks **36** are advantageous particularly when the surgeon or orthopedist has pushed the extractor into the region of the spongiosa, but the spongiosa is no longer capable of offering the extractor the required support for twisting the tissue column off the bottom on which it is still anchored. With a longer twist lock **36**, however, this twist lock extends at least into a region of the tissue column that offers sufficient support to make sure it is possible to twist off the tissue column even if, due to the composition of the spongiosa, it would be impossible with a short twist lock **36**.

Unlike extractor guide **30** (Figs. 6 and 7), extractor guide 30.1 is not equipped for a precise extraction angle α and cannot be affixed to a removal site. For this reason, it is not very suitable as a guide for a drill. Rather, its function is to provide the surgeon with an another holding means, in addition to handle **83**, for holding extractor 31.1 during the extraction of a tissue column, whereby in guide 30.1 extractor 31.1 is freely rotatable and, at the same time, it prevents an undesired spreading of the two extractor parts by slit **82** down to the region of the pointed end. /26

Implant guide 40.1 is also not equipped for being affixed to the defect region. It also has opposing windows **80**, by means of which the rotational position can be determined by aligning a tissue column with the window in extractor 31.1 during implantation. The inner diameter of implant guide 40.1 corresponds to the outer diameter of extractor 31.1 only at a distal end region and is otherwise larger. In this way,

spreading of the two extractor parts separated by slits **82** is possible during implantation. For the above-mentioned spreading of extractor parts, plunger 37.1 has a conical region **84**.

By spreading the extractor parts during implantation, the friction between extractor and tissue column is reduced and, thus, the pressure on the cartilage layer of this tissue column, which is necessary for pushing it out of the extractor, is less, so that the tissue column is handled in a more gentle manner.

Plunger 37.1 also has a handle **85** for convenient handling and, at the same time, it assures that the plunger can be pushed in only to the pointed end of extractors 31.1.

The characteristics of instrument parts 31.1,30.1,40.1 and 37.1 /27 in accordance with Figs. 13 through 16 may be combined in any desired manner with characteristics of functionally identical instrument parts **31, 30, 40, 37** in Figs. 7 and 8.

Figure 17 shows instrument parts 31.1, 40.1, and 37.1 of Figs. 13,15 and 16 in three-dimensional representation.

Figures 18 and 19 show additional exemplary embodiments of an implant guide 40.2 and a plunger 37.2, which are similar to implant guide 40.1 and plunger 37.1 of figures 15 and 16. Here, extractor 31.1 and extractor guide 30.1 can be kept essentially unchanged in the form shown in Fig. 13 and Fig. 14, in particular, however, twist locks **36** can extend over the entire length of extractor 31.1.

As seen in Fig. 13, handle **83** has on its underside a stop pin **830** extending downward. This stop pin **830** is of no further importance for removing the tissue column at the harvesting site, except that extractor guide 30.1 (Fig. 14) can have a corresponding recess **831** for accommodating this stop pin **830** which then, together with the stop pin, forms an anti-twist stop. On the other hand, stop pin **830** can be of considerable importance if the implant guide is of the proper design. In order to explain this importance, for the examination below stop pin **830** can have, for example, a height of 3 mm (measured from the underside of handle **83**).

If a tissue column has been removed at the harvesting site with the help of extractor 31.1 and the tissue column is in extractor 31.1 and, for example, is flush with extractor 31.1 at the bottom, /28 then this tissue column -- as explained above -- should be implanted in a corresponding borehole or recess at the defect site. This implantation is performed in such a way that the tissue column fits into the borehole at the defect site with a slight press fit. As

previously explained, it is of particular advantage to the success of such an implantation/transplantation, if the original shape of the cartilage (i.e., the shape before the defect appeared) is recreated as true to nature as possible, so that after the healing process the cartilage has its original shape as much as possible.

To achieve this, it may be necessary -- depending on the size of the defect -- with the help of implant guide 40.2 and plunger 37.2 (Fig. 18 and Fig. 19) for the tissue column to be pushed all the way to the bottom of the borehole that has been made at the defect site or for the tissue column to be at a certain distance from the bottom of the borehole after it has been pushed in, so that the original shape of the cartilage can be recreated as naturally as possible. However, in no case should the tissue column be pushed in deeper than the bottom of the borehole. This danger is present, in particular, when the bottom of the borehole lies inside the (porous) spongiosa. To achieve or avoid all this, the surgeon or orthopedist should be provided with a simple instrument.

For this purpose, implant guide 40.2 has on its proximal end surface (Fig. 18) two recesses **832** and **833**, e.g., oppositely arranged, recess **832** of which, for example, has a depth of 1 mm and recess **833** a depth of 3 mm. If during implantation the tissue column containing extractor 31.1 (Fig. 13) with stop pin **830** is first inserted into implant guide 40.2. (Fig. 18), then stop pin **830** can be brought into three different positions relative to implant guide 40.2.

In the first position, stop pin **830** comes to rest in recess **833**. /29 Since stop pin **830** in this embodiment has a length of 3 mm and recess **833** likewise has a depth of 3 mm, the underside of handles **83** of extractor 31.1 comes to lie flat on the proximal face surface of implant guide 40.2.

In the first position, stop pin **832** comes to rest in recess **833**. It has a depth of 1 mm, so that the underside of handle **83** of extractor 31.1 comes to rest 2 mm above the proximal face surface of implant guide 40.2 when stop pin **830** is on the bottom of recess **832**.

Finally, in the third position, stop pin **830** comes to rest in neither of the two recesses **832** or **833**, but lies on the proximal face surface of implant guide 40.2. In this position, the underside of handle **83** of extractor 31.1 comes to rest 3 mm above the proximal face surface of implanting guide 40.2.

If the surgeon inserts the extractor into one of the three positions in implant guide 40.2, then implant guide 40.2 is placed on the site of the defect, namely in such a way that the distal face

surface of implant guide 40.2 is placed on the subchondral bone around the previously prepared borehole. Subsequently, the plunger is used to push the tissue column out of the extractor and into the borehole.

The plunger is basically made such that with the plunger completely inserted into the extractor, the underside of the plunger handle rests on the proximal face surface of the handle of extractor 31.1. In this state, the distal end of the plunger is flush with the /30
distal end of the extractor -- the distal end of the plunger has pushed the tissue column completely out of the extractor, but not necessarily completely out of implant guide 40.2. That depends on the position in which the extractor has been inserted into implant guide 40.2.

If stop pin 830 of the extractor has been plunged to the stop in recess **833** of implant guide 40.2 (first position), then plunger 37.2 has pushed the tissue column completely out of implant guide 40.2 (because the distal end of the extractor is then flush with the distal end of the implant guide) and, thus, it has normally pushed the tissue column to the bottom of the borehole at the site of the defect and the tissue column does not extend above the subchondral bone.

If stop pin **830** of extractor 31.1 has been plunged into recess **832** to the stop (second position), then the plunger, which has been completely plunged into the extractor, has pushed the tissue column completely out of extractor 31.1, to be sure, but not completely out of implant guide 40.2 (because the distal end of the extractor is not flush with the distal end of the implant guide), rather there remains a length of 3 mm (length of stop pin **830**) minus 1 mm (depth of borehole **832**), i.e., a length of 2 mm, by which the tissue column still extends into implant guide 40.2. The tissue column then projects above the subchondral bone by this amount, but this may be desirable in the case of larger defects, for a natural imitation of the original cartilage shape.

If stop pin **830** is on the proximal face surface of extractor 31.1 (third position), there is an amount of 3 mm, by which the tissue column still extends into implant guide 40.2 or stands above the subchondral bone at the site of the defect when the plunger is /31
completely inserted. It is clear that these values for the depth of recesses **832** and **833** are to be seen only as examples, while other values are obviously possible, as well. Depending on the circumstances at the defect site, the surgeon or orthopedist can decide how far he wants to push the tissue column into the borehole.

Compared to plunger 37.1 (Fig. 16), plunger 37.2 shown in Fig. 19 has another feature. The handle of plunger 37.2 comprises two parts,

namely an upper handle part **851**, which is firmly attached to the shaft of the plunger, and a lower handle part **852**, which moves along the shaft, whose outer wall is made conically tapered, as viewed in the distal direction. This lower handle part **852** is movable along the shaft as far as a bead **853**. When the shaft of plunger 37.2 is inserted into extractor 31.1, lower handle part **852** can be moved into the extractor and, with the help of its conical outer surface, it can slightly spread extractor 31.1, which as we know has longitudinal slits. However, lower handle part **852** can be pushed only until the underside of lower handle part **852** lies on the proximal face surface of handle **83** of extractor 31.1. When extractor 31.1 is slightly spread in this way, pushing tissue column further out pushing the tissue column into the borehole is facilitated, since the slightly spread extractor makes it easier to push the tissue column out of the extractor and into the borehole at the site of the defect. To make pushing the tissue column out of the extractor easier, the surgeon or orthopedist can also use a small hammer, with which he lightly taps on upper handle part **851**, until upper handle part **851** lies against lower handle part **852**, which in turn lies on the proximal face surface of handle **83** of extractor 31.1.

Claims /32

1. An instrument set for repairing endochondral or osteochondral defects (20) by implantation of tissue columns (2), which have on one face side a vital cartilage layer (2'), said instrument set having instruments for making defined, cylindrical holes (21) for implanting tissue columns (2) in the region of defect (20), instruments for extracting tissue columns (2) from vital tissue or for shaping tissue columns (2) from an in vitro cultivated cartilage layer, and instruments for implanting tissue columns (2) into cylindrical holes (21) that have been made, characterized in that the instrument set also has at least one additional instrument from an instrument group, whereby said instrument group essentially consists of the following instruments: instruments for increasing the precision of the parallelism and positioning of cylindrical holes (21), instruments for determining the original cartilage surface (22) in the region of defect, instruments for determining the distance between the base surface of a cylindrical hole (21) that has been made and original cartilage surface (22), instruments for extracting tissue columns with a predetermined angle (α) between the cartilage surface and the column axis, and instruments for producing an implant from an in vitro cultivated cartilage layer (50) for filling the gaps in the cartilage surface repaired with tissue columns (2).

2. An instrument set as recited in Claim 1, characterized in /33

that the instruments for increasing precision with respect to the parallelism and positioning of holes (21) are guide instruments (10,11,12) for stamping or drilling instruments for making holes (21), said guide instruments having means for fixed positioning in the region of a defect that is to be repaired.

3. An instrument set as recited in Claim 1, characterized in that the instruments for determining the original cartilage surface are a plurality of profile gauges (23).

4. An instrument set as recited in Claim 3, characterized in that the instruments for determining the distance between the particular cartilage surface (22) and the base surface of a cylindrical hole (21) being made have surface templates (24) of profile gauges (23) with measurement holes (26) associated with the holes (21) that are produced.

5. An instrument set as recited in Claim 1 or 3, characterized in that the instruments for extracting tissue columns (2) at a predetermined angle (α) between cartilage surface and column axis at a removal site have means for guiding the extraction instruments that are affixable and positionable at the predetermined angle (α).

6. An instrument set as recited in Claim 1, characterized in that the instruments for producing an implant from an in vitro cultivated cartilage layer (50) for filling the gaps between implanted tissue columns (2) are made in the form of stamping instruments (60,61) or cutting instruments.

7. An instrument set as recited in Claim 6, characterized in that the set has additional instruments (70,72) for measuring the thickness of cartilage layer (50). /34

8. An instrument for increasing precision with regard to parallelism and positioning of cylindrical holes (21) to be made in the region of an endochondral or osteochondral defect (20), for implanting tissue columns (2) with a vital cartilage layer (2'), characterized in that it is made in the form of a guide instrument (10,11,12) that is affixable and positionable in the region of defect (20), for a stamping or drilling instrument.

9. An instrument as recited in Claim 8, characterized in that it has a circular guide (10) and at least one stamping or drilling guide (11, 12) that is positionable in circular guide (10).

10. An instrument for determining an original cartilage surface (22) in the region of an endochondral or osteochondral defect (20)

that is to be repaired, characterized in that it comprises a plurality of profile gauges (23).

11. An instrument for determining the distance between the base surface of a cylindrical hole (21) made in the region of an endochondral or osteochondral defect (20) and an original cartilage surface (22), characterized in that it has means for recreating the original cartilage surface and a measuring rod.

12. An instrument as recited in Claim 11, characterized in that /35
the means for recreating original cartilage surface (22) are surface templates (24), which have measurement holes (26) that are correlated with the cylindrical holes (21) that are made.

13. An instrument as recited in Claim 12, characterized in that surface template (24) can be attached to a circular guide (10) that is affixable and positionable in the region of defect (20).

14. An instrument for extracting tissue columns (2) at a predetermined angle (α) between the cartilage surface and the column axis for implantation in the region of an endochondral or osteochondral defect (20), characterized in that it has a means for guiding instruments for extracting tissue columns (2), said means being affixable and positionable at the angle (α) at a removal site.

15. An instrument as recited in Claim 14, characterized in that the means for guiding is made essentially as a tubular extractor guide (30,30.1) and the extracting instrument is made as an extractor (31,31.1) that can be inserted into extractor guide (30,30.1).

16. An instrument as recited in Claim 15, characterized in that extractor (31.1) has windows.

17. An instrument as recited in Claim 15 or 16, characterized in that extractor (31.1) is divided by two slits (82) into two extractor parts that are connected by a distal extractor region to a pointed end edge.

18. An instrument as recited in one of the Claims 15 through /36
17, characterized in that extractor guide (30) has an application flange (32), which forms the predetermined angle (α) with the tube axis.

19. An instrument for producing an implant from an in vitro cultivated cartilage layer (50) for filling the gaps in a cartilage surface repaired with tissue columns (2), characterized in that the

instrument is made in the form of stamping instrument (60,61) or as a cutting instrument.

20. An instrument as recited in Claim 19, characterized in that is made in the form of stamping instrument (60,61) and has an application surface (60) in the form of an original cartilage surface (22) and has a stamping form (61) with punch blades (62).

21. An instrument for determining the thickness of an in vitro cultivated cartilage layer (50), characterized in that it has a measuring unit (70) with molds (71) of various depths and has a weighting unit (72).

22. A method of repairing endochondral or osteochondral defects (20) by implanting tissue columns (2) having on one face side a vital cartilage layer (2') into cylindrical holes in the region of the defect, characterized in that for precise guidance of stamping or drilling instruments used to make cylindrical holes (21), a guide instrument (10,11,12) is positioned and affixed in the region of defect.

23. A method of repairing endochondral or osteochondral defects (20) by implanting tissue columns (2), having on one face side a vital cartilage layer (2') into cylindrical holes (21) in the region of the defect, characterized in that before the repair the original cartilage surface (22) is determined and that this original cartilage surface (22) is reconstructed by the repair. /37

24. A method as recited in Claim 23, characterized in that the distance between the base surface of a cylindrical hole (21) that is made and the original cartilage surface (22) is determined and that the axial length of the tissue column (2) that is to be implanted in hole (21) is adapted to this distance.

25. A method of repairing endochondral or osteochondral defects (20) by implanting tissue columns (2) having on one face side a vital cartilage layer (2') into cylindrical holes (21)made in the region of the defect, characterized in that an angle (α) between a cartilage surface (22) that is to be made and the axis of a cylindrical hole (21) is determined and that a tissue column (2) that is to be implanted in hole (21) has an identical angle (a) between the column axis and the cartilage surface and is implanted at a defined rotational position.

26. A method of repairing endochondral or osteochondral defects (20) by implanting tissue columns (2) having on one face side a vital cartilage layer (2') into cylindrical holes (21) made in the region of

the defect (20), characterized in that gaps in the cartilage layer between implanted tissue columns (2) and between the edge of defect (20) and implanted tissue columns (2) is filled by an additional implant made of an in vitro cultivated cartilage layer (50).

27. A method as recited in Claim 26, characterized in that /38
cartilage layer (50) is stamped or cut for implantation in a shape or form with holes for the implanted tissue columns (2).

28. A method as recited in one of the Claims 26 or 27, characterized in that the thickness of the in vitro cultivated cartilage layer (50) is determined and that for the additional implant, which is made of the cartilage layer, a hole is made in the defect region with a minimal depth, whereby the minimal depth essentially corresponds to the thickness of the in vitro cultivated cartilage layer.

29. A method as recited in one of the Claims 26 through 28, characterized in that the implant made of in vitro cultivated cartilage layer (50) is backfilled at least in part with a filler material (51).

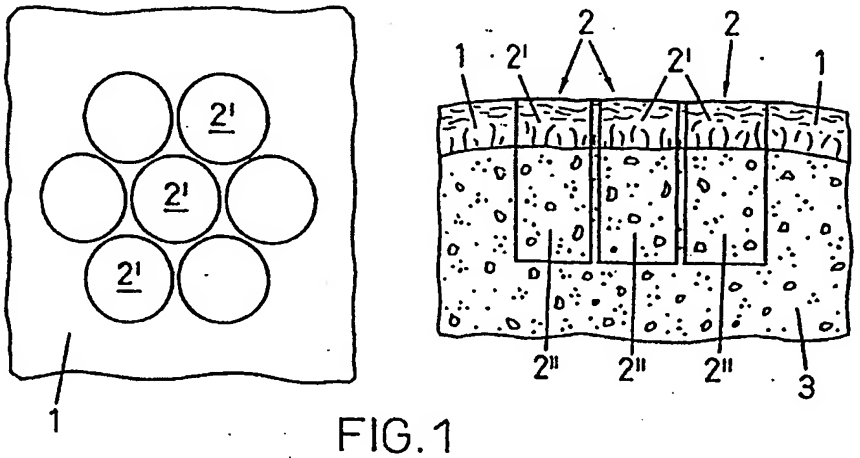

FIG. 1

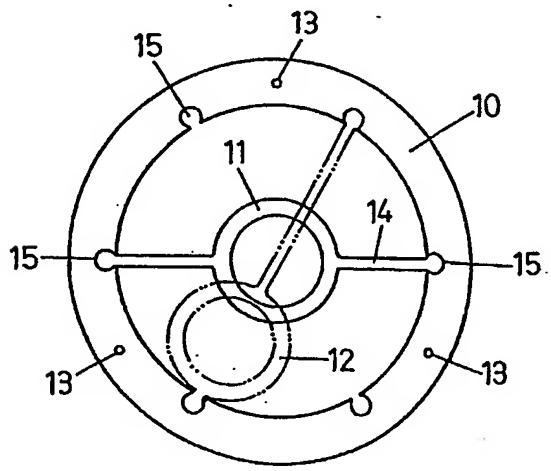

FIG. 2

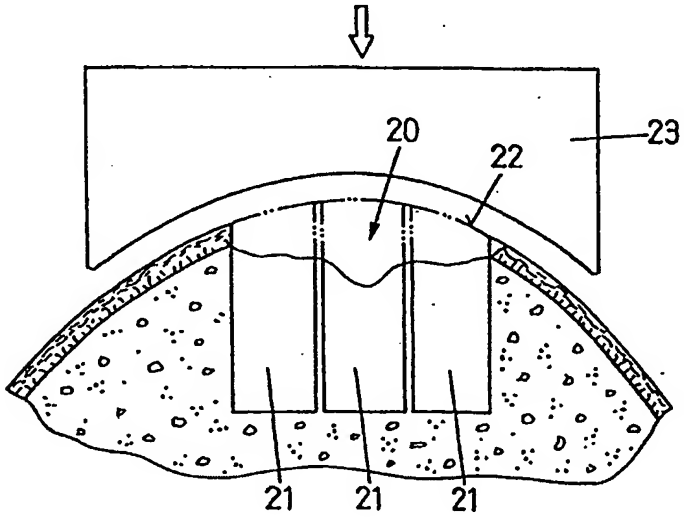

FIG. 3

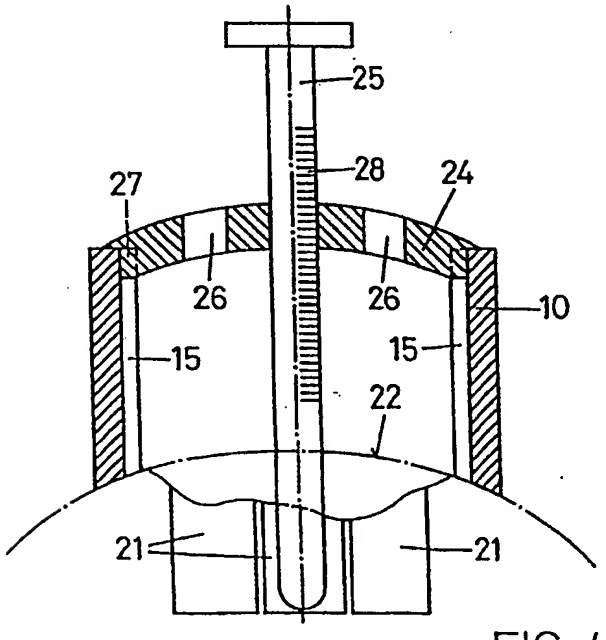

FIG. 4

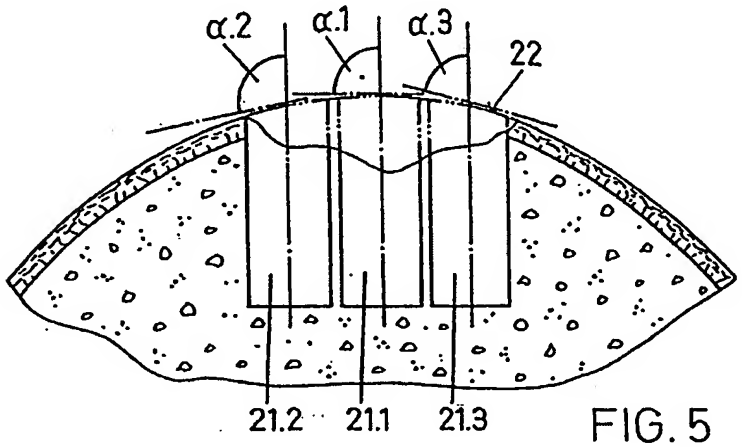

FIG. 5

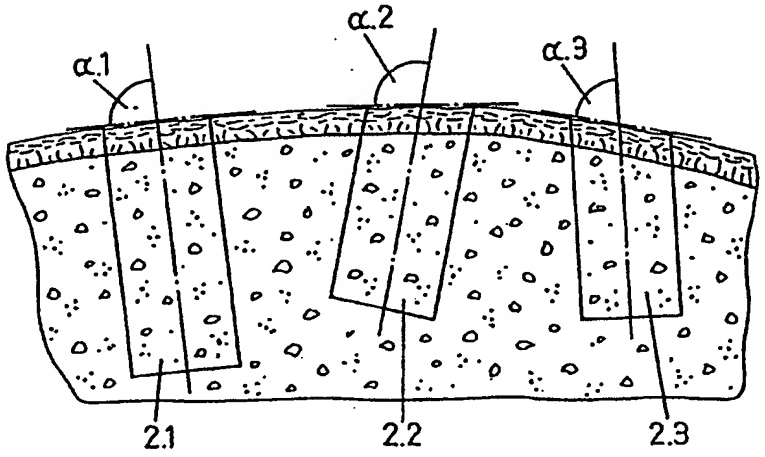

FIG. 6

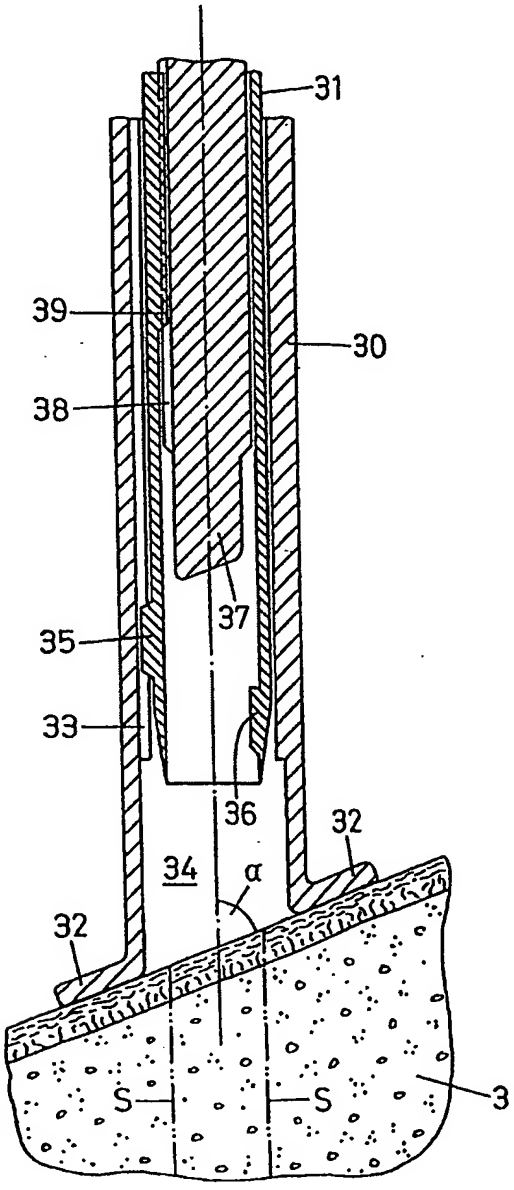

FIG. 7

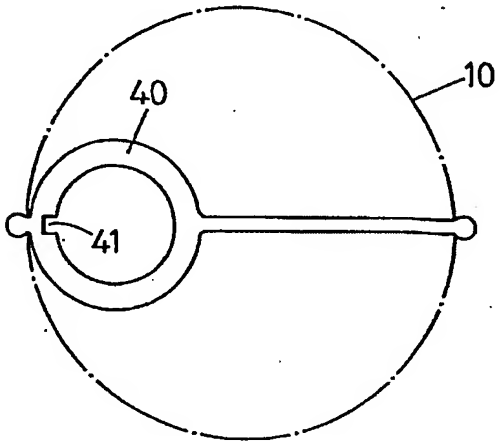

FIG. 8

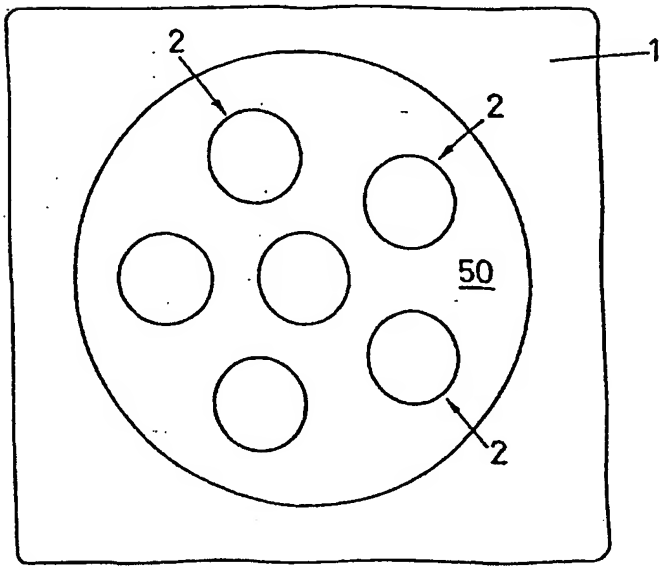

FIG. 9

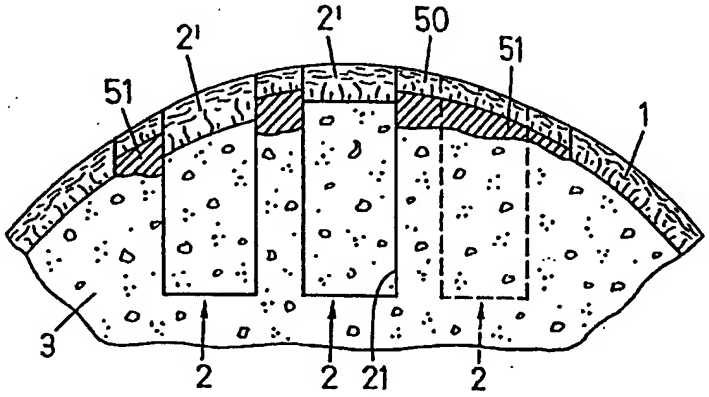

FIG. 10

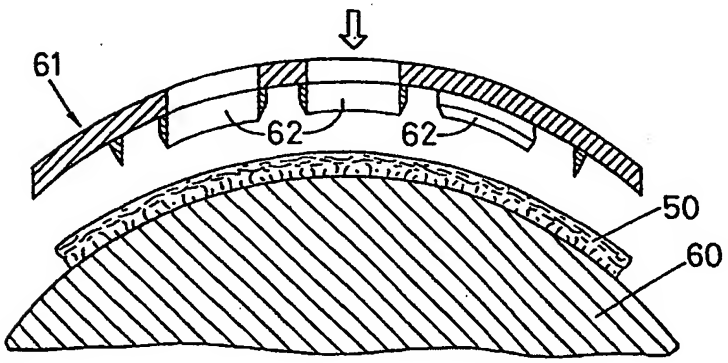

FIG. 11

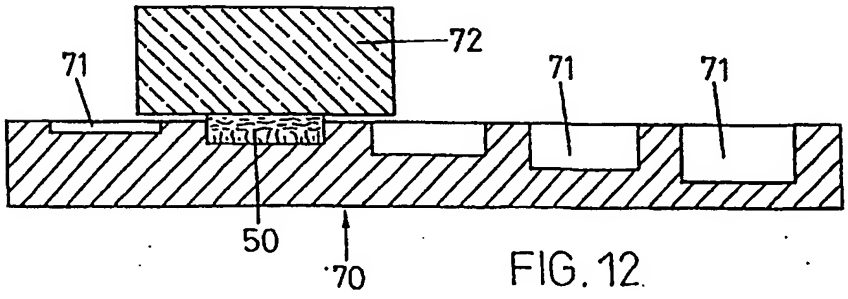

FIG. 12

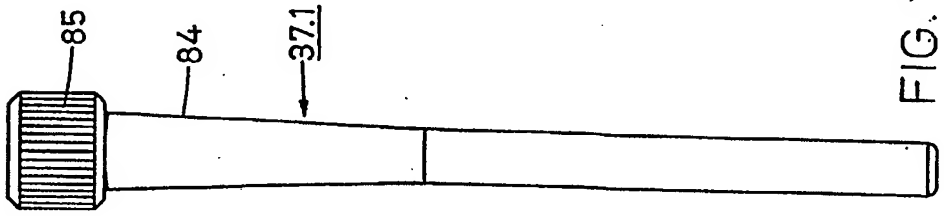

FIG. 16

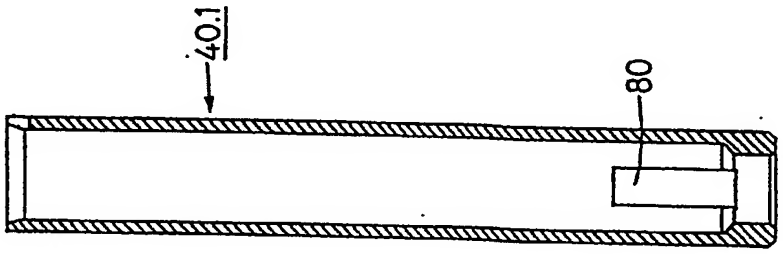

FIG. 15

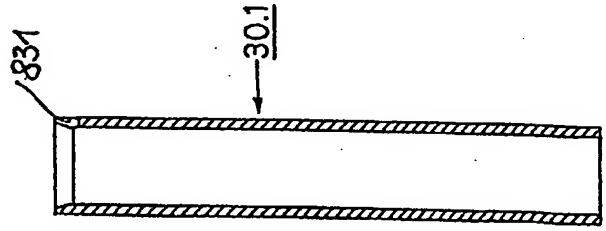

FIG. 14

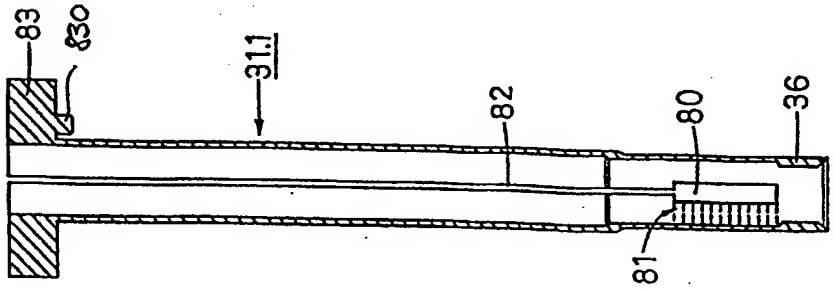

FIG. 13

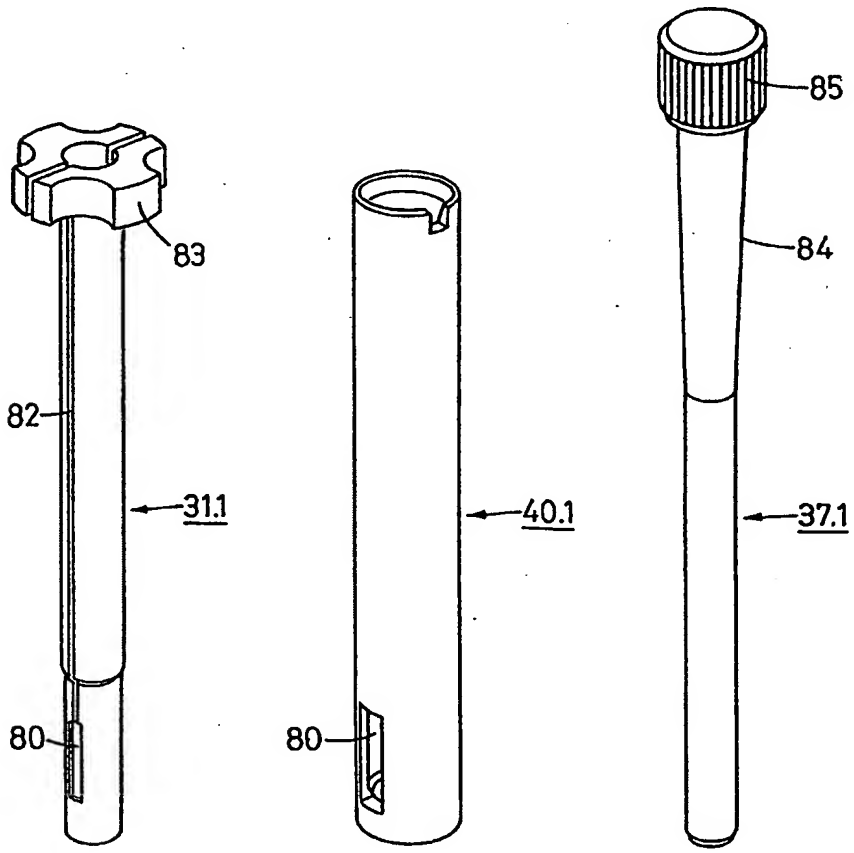

FIG. 17

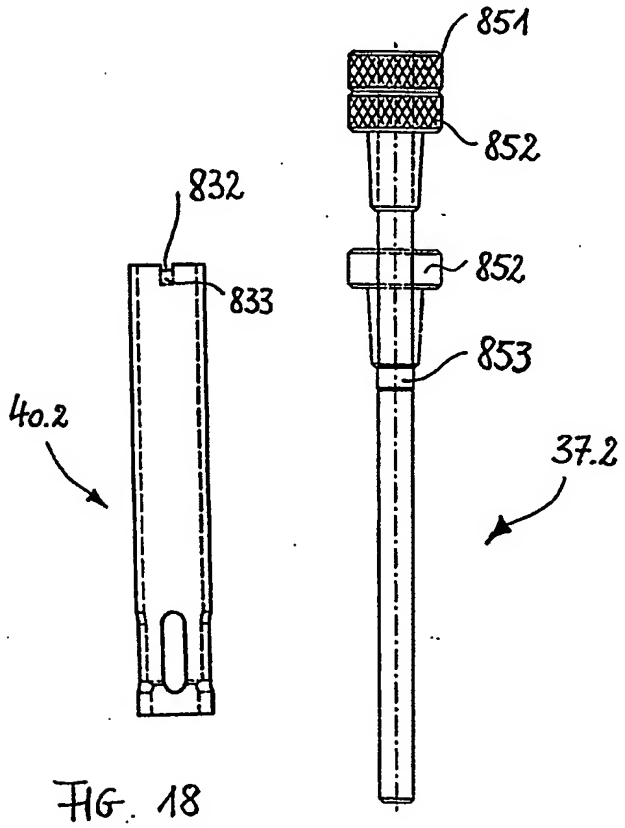

FIG. 18

FIG. 19